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10/553,656	10/14/2005	Ana Isabel Sanz Molinero	BJS-4982-13	5797

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EXAMINER

KUMAR, VINOD

ART UNIT	PAPER NUMBER
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1638

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/553,656	Applicant(s) SANZ MOLINERO, ANA ISABEL	
	Examiner VINOD KUMAR	Art Unit 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 September 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,4,6,7,9,10,25,27,28,30,31,33 and 34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3-4,,6,7,9,10,25,27,28,30,31,33 and 34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 April 2008 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>9/21/2009</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of objections and rejections

1. Applicant's amendment filed 9/21/2009 is entered.
2. Claims 1, 3-4, 6-7, 9-10, 25, 27-28, 30-31 and 33-34 are pending.
3. Claims 2, 5, 8, 11-24, 26, 29 and 32 are cancelled.
4. Claims 1, 3-4, 6-7, 9-10, 25, 27-28, 30-31 and 33-34 are examined on merits in the present Office action.
5. Objections to claims 1, 3-4, 6-7, 9-10, 25, 27-28, 30-31, 33 and 34 made in the Office action of 5/21/2009 are withdrawn in light of claim amendments filed in the paper of 9/21/2009. Objection to claim 32 made in the Office action of 5/21/2009 is also withdrawn in light of cancellation of claim 32 filed in the paper of 9/21/2009. However, due to claim amendment filed in the paper of 9/21/2009, new objections to claims 6-7 and 30-31 have been necessitated as set forth in this Office action.
6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
7. Rejection of claims 1, 3-4, 6-7, 9-10, 25, 27-28, 30-31, 33 and 34 under 35 U.S.C. 112, second paragraph is withdrawn in light of claim amendments filed in the paper of 9/21/2009. Rejection of claim 32 under 35 U.S.C. 112, second paragraph is also withdrawn in light of cancellation of claim 32 filed in the paper of 9/21/2009.
8. Rejections of claims 1, 3-4, 6-7, 9-10, 25, 27-28, 30-31, 33 and 34 under 35 U.S.C. 112, first paragraph are withdrawn in light of claim amendments filed in the

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paper of 9/21/2009. Rejections of claim 32 under 35 U.S.C. 112, first paragraph are also withdrawn in light of cancellation of claim 32 filed in the paper of 9/21/2009.

9. Rejection of claim 32 under 35 U.S.C. 103(a) as being unpatentable over Basel et al. (WIPO Publication No. WO 98/36084, Published 20 August, 1998, Applicant's IDS) in view of Zhou et al. (Mol. Gen. Genet. 248:318-328, 1995) is withdrawn in light of cancellation of claim 32 filed in the paper of 9/21/2009.

Claim Objections

10. Claims 6-7 and 30-31 are objected to because of the following informalities:

Claim 6 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim, or amend the claim to place the claim in proper dependent form, or rewrite the claim in independent form. Parent claim 1 is directed to a nucleic acid encoding SEQ ID NO: 2. Since there is only one SEQ ID NO: 2 which is isolated from a plant species, and which is a type 2 metallothionein protein, claim 6 therefore fails to limit the scope of parent claim 1.

Claim 7 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim, or amend the claim to place the claim in proper dependent form, or rewrite the claim in independent form. Parent claim 1 is directed to a nucleic acid encoding SEQ ID NO: 2. Since there is only one SEQ ID NO: 2 which is isolated from a plant species, claim 7 therefore fails to limit the scope of parent claim 1 or claim

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6.

Claim 30 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim, or amend the claim to place the claim in proper dependent form, or rewrite the claim in independent form. Parent claim 25 is directed to SEQ ID NO: 1 encoding SEQ ID NO: 2. Since there is only one SEQ ID NO: 2 which is isolated from a plant species, and which is a type 2 metallothionein protein, claim 30 therefore fails to limit the scope of parent claim 25.

Claim 31 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim, or amend the claim to place the claim in proper dependent form, or rewrite the claim in independent form. Parent claim 25 is directed to SEQ ID NO: 1 encoding SEQ ID NO: 2. Since there is only one SEQ ID NO: 2 which is isolated from a plant species, claim 31 therefore fails to limit the scope of parent claim 25 or claim 30.

Objection to claims 6-7 and 30-31 has been necessitated due to the Applicant's claim amendment filed in the paper of 9/21/2009.

Claim Rejections - 35 USC § 103

11. Claims 1, 3-4, 6-7, 9-10, 25, 27-28, 30-31, 33 and 34 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Basel et al. (WIPO Publication No. WO 98/36084, Published 20 August, 1998, Applicant's IDS) in view of Zhou et al. (Mol. Gen.

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Genet. 248:318-328, 1995) for the reasons of record stated in the Office action mailed on 5/21/2009. Applicant traverses the rejection in the paper filed on 9/21/2009.

Applicant argues that Basel et al. do not teach that expression of metallothionein in a plant would result in enhanced plant growth. Applicant further argues that Basel et al. teach that carbonic anhydrase when used in combination of metal binding proteins may provide beneficial effect to the plant. Applicant further argues that there is no motivation in Basel et al. that would lead a person of ordinary skill to express a metallothionein protein in a plant from a constitutive promoter (response, paragraph bridging pages 6 and 7).

Applicant's arguments are carefully considered but are deemed to be unpersuasive.

Applicant's attention is drawn to the paragraph bridging pages 36 and 37 of Basel et al., wherein the reference states:

"The present inventors have discovered that the metal binding protein, metallothionein, enhances the growth rates of a number of plants. This therefore indicates that the class of metal binding proteins naturally occurring in various animals offers an advantage in growth rates by reducing the level of toxic cations in growing plant cells."

Applicant's attention is also drawn to claims 17 and 18 on page 129 of Basel et al., wherein the reference clearly teaches a method of enhancing plant growth by expressing a metallothionein protein in a transgenic plant.

Thus Applicant is not on point in suggesting that reference only teaches expressing a metal-binding protein (e.g. metallothionein) in combination with a carbonic

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anhydrase. As discussed above, the reference does teach increasing plant growth by overexpressing a metallothionein protein by itself in a transgenic plant.

Applicant's attention is also drawn to page 2, lines 11-23; page 9, lines 7-14; page 35, line 6; page 37, line 12; SEQ ID NO: 7, wherein Basel et al. teach a method of making a transgenic plant with increased growth and development comprising introducing and overexpressing a nucleic acid sequence encoding a metallothionein, and wherein the nucleic acid is expressed under a constitutive promoter.

Applicant while admitting that Zhou et al. do teach existence of metallothionein gene family in *Arabidopsis* that can be divided into two groups: MT1 and MT2, and which are differentially expressed, however, argues that said differential expression is not important because instant nucleic acid encoding metallothionein protein of SEQ ID NO: 2 is expressed under a constitutive promoter. Applicant further argues that given the similarity in expression pattern between MT2a and MT2b in Zhou et al., one of ordinary skill would not have been motivated to have chosen MT2a (100% identity with instant SEQ ID NO: 2) rather than MT2b (response, line 15 of page 7 through line 8 of page 8).

Applicant's arguments are carefully considered but are deemed to be unpersuasive.

Applicant's attention is drawn to page 318, abstract; page 322, figure 3; page 324, figures 6 and 7; page 326, 2nd column through the end of 1st column of page 327 of Zhou et al., wherein the reference clearly teach a nucleic acid sequence encoding *Arabidopsis* type 2 metallothionein protein (MT2a) which has 100% sequence identity to

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instant SEQ ID NO: 2. The reference further teaches that nucleic acid sequences encoding members of metallothionein proteins are differentially regulated. The reference specifically teaches that compared to other members of the gene family, MT2a is overexpressed in the mature leaves and inflorescence.

It is important to note that issue is not whether Zhou et al. teach expression of MT2a (SEQ ID NO: 2) from a constitutive promoter. Rather, the issue is whether one of ordinary skill in the art would have been obviously motivated in overexpressing any metallothionein protein, including MT2a of Zhou et al. in a plant. In the instant case, given that Basel et al. do provide a strong motivation in expressing a metallothionein protein from a constitutive promoter in a plant to increase plant growth and development as discussed above, it would have been obvious and within the scope of an ordinary skill in the art to express a metallothionein protein, such as MT2a (100% identity to instant SEQ ID NO: 2) of Zhou et al. in a plant to arrive at the claimed invention with a reasonable expectation of success.

It is therefore, maintained that it would have been prima facie obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the method of making a transgenic plant with increased growth and development as taught by Basel et al., to substitute the coding sequence encoding Basel et al. metallothionein protein with a nucleotide sequence encoding Zhou et al. type 2 metallothionein protein to obtain a transgenic plant and transgenic seed expressing Zhou et al. metallothionein protein.

It is further maintained that given that Basel et al. teach overexpressing a metallothionein protein in a plant improves growth and development, and Zhou et al.

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teach that type 2 metallothionein proteins (MT2a, in particular) are highly expressed in tissues like leaf and inflorescence, it would have been obvious and within the scope of an ordinary skill in the art to have been motivated to express Zhou et al. sequence in a plant to obtain transgenic plants having improved growth and development with a reasonable expectation of success. It would have been obvious that increased growth and development would have improved yield, such as seed yield with a reasonable expectation of success. Obviously, one of ordinary skill in the art would have been motivated to select transgenic plants overexpressing transgenic nucleic acid encoding Zhou et al. metallothionein and which exhibited improvement in any plant characteristics, including seed yield and/or biomass. It would have been obvious to one of ordinary skill in the art that any increase in seed yield would have been reflected in terms of increase in total number of seeds and/or increased total weight of seeds,

It is important to note that it would have been obvious that one of ordinary skilled in the art would have also observed increased seed yield and biomass in the transgenic plant overexpressing Zhou et al. type 2 metallothionein protein because increased seed yield and biomass would have been due to the over-expression of Zhou et al. type 2 metallothionein (100% identity to instant SEQ ID NO: 2) in the transgenic plant.

It is thus maintained that while one of ordinary skill in the art would have expressed Zhou et al. MT2a protein in a plant using any method of plant transformation including the one taught by Basel et al. for the purpose of obtaining a transgenic plant with improved growth and development, it would have been obvious that said plant would have also exhibited any other characteristics including increased seed yield

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and/or biomass traits with a reasonable expectation of success because these traits are directly related to the property of Zhou et al. protein over-expression in said transgenic plant.

In response to Applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, it would have been obvious and within the scope of an ordinary skill in the art to combine the teachings of Basel et al. and Zhou et al. as discussed above to arrive at the claimed invention with a reasonable expectation of success.

It is important to note that obviousness does not require an absolute certainty of success but merely a reasonable expectation thereof, so long as the motivation or suggestion to combine the teaching of the cited references is known or disclosed in the prior art and is obvious to one skilled in the art and this is sufficient to establish a *prima facie* case of obviousness. In the instant case, one of ordinary skill in the art would have used teachings of the prior art as discussed above to arrive at the claimed invention with a reasonable expectation of success.

Thus, it is maintained that the claimed invention as a whole is *prima facie* obvious over the combined teachings of the prior art.

Conclusions

12. Claims 1, 3-4, 6-7, 9-10, 25, 27-28, 30-31, 33 and 34 remain rejected.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vinod Kumar whose telephone number is (571) 272-4445. The examiner can normally be reached on 8.30 a.m. to 5.00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Vinod Kumar/
Primary Examiner, Art Unit 1638